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EXAMINER	
HUYNH, PHUONG N	

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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,470	SCHOLZ, MARTIN	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2009; 10/1/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6,9,11-15 and 18-25* is/are pending in the application.

4a) Of the above claim(s) *14,15,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-6, 9, 11-13 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, 5-6, 9, 11-15 and 18-25 are pending.

2. Claims 14-15, 24 and 25 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

3. Claims 1, 3, 5-6, 9, 11-13 and 18-23, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is specific antigen from a specific *virus* are being acted upon in this Office Action.

4. The species restriction mailed January 5, 2009 is hereby withdrawn.

5. In view of the amendment filed March 5, 2009 and October 1, 2008, the following objection and rejection remain.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3, 5-6, 9, 11-13 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any cell components, (2) any cell coating, (3) any synthetic antigen is obtained from any viruses, any fragment of cytomegalo viruses embedded in a soluble matrix and a least one carrier for

generating leukocyte stimulation or any fragment of any virus of the family of herpes, for generating leukocyte stimulation and/or induction of immunological tolerance to such antigen.

The specification discloses only the specific biocompatible materials as a carrier selected from the group consisting of polyurethanes, polycarbonates, polystyrene, Monocryl (poliglecaprone 25, PDS-2 (polydioxanon), Maxon (polyglyconate), Vicryl (polyglactin-910), Dexon-Plus (polyglycolic acid), glass, gut skins, or sponges, see page 5-6. The specification discloses the soluble matrix is made of polyethylene glycol (PEG) or a matrix comprising PEG and a long chain sugar compound selected from the group consisting of starch, cellulose and glycogen. The soluble matrix preferably comprises 50-90 wt.%, more preferably 60-80 wt.% of one or more long chain sugar compounds and 10-50 wt.%, preferably 20-40 wt.% of a polyethylene glycol, based on the total of long chain sugar compounds and polyethylene glycol, see page 7 of specification. PEG is preferably used as an aqueous solution, wherein a solution of about 1-10 wt.%, preferably about 5 wt.%, of a PEG having e.g. a molecular weight of 15-20 kD is used. The concentration can be up to 20 wt.% of a PEG with a low molecular weight (e.g. about 6 kD), see page 7. The specification discloses antigen from virus (CMV) is embedded or covalently linked to polyethylene glycol (PEG) using coupling agent anhydroalkoxysilance also known as 3-triethoxysilyl propyl succinic acid anhydride (GENIOSIL®), covalent bond selected from the group consisting of cyanogen bromide, cyanoboro hydride, agarose, silance and a combination thereof, see page 13.

The specification exemplifies a leukocyte stimulation matrix comprising a) 10 mg of polyurethane foam as a carrier, b) a solution of polyethylene glycol having a molecular weight of 15-20 kd, and c) UV-inactivated cytomegalovirus virus antigen embedded into polyethylene glycol, see page 19 or UV-inactivated cytomegovirus antigen covalently bounds to the carrier polyurethane foam using coupling agent 3-triethoxysilyl propyl succinic acid anhydride (GENIOSIL®). The carrier with covalently bound antigens showed a decreasing immune reaction (CD69/INF-γ). In contrast, the antigens embedded in the soluble matrix could induce antigen specific T-cell mediated immune response in whole blood was constant over time. The specification defines component to be embedded into the soluble matrix are antigen, MHC molecules, co-stimulatory factors, membrane fragment of Antigen presenting cell (APC), bacteria, viruses and a combination thereof, see page 8.

At the time of filing, applicants are not in possession of any leukocyte stimulation matrix having any "cell components", or any "cell coating" or any combinations thereof, any synthetic antigen obtained from any virus, an bacteria, any fungi, any tumor, any allergens, any endogenous tissue, any fragment of any virus from the family of herpes viruses other than membrane fragments of Antigen presenting cell (APC) and viral antigen from cytomegalo virus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

As discussed above, the skill artisan cannot envision the detailed structure of the encompassed genus of cell component, cell coatings, synthetic antigen obtained from any viruses, synthetic antigen obtained from any bacteria, synthetic antigen obtained from any fungi, synthetic antigen obtained from any tumors, synthetic antigen obtained from any allergens, synthetic antigen obtained from any endogenous tissue and/or synthetic antigen obtained from any MHC molecules for the claimed leukocyte stimulation matrix that either stimulation of leukocyte, or induction of an immunological tolerance, or stimulation of leukocyte and the induction of any immunological tolerance.

Adequate written description requires more than a mere statement that it is part of the invention. The antagonist itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provides only the bovine sequence.

In this case, the specification provides only one leukocyte stimulation matrix comprising viral antigen from cytomegalovirus (CMV) embedded or covalently linked to soluble matrix polyethylene glycol (PEG) using coupling agent anhydroalkoxysilance also known as 3-triethoxysilyl propyl succinic acid anhydride (GENIOSIL®). The pegilated viruses covalently bound with silane to cellulose or non-covalently for leukocytes toward CMV antigen and/or induction of immunological tolerance toward cytomegalovirus.

Therefore, only leukocyte stimulation matrix comprising the specific carrier, the specific soluble matrix and the specific CMV viral antigen that stimulate leukocyte meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' arguments filed April 3, 2009 and October 1, 2008 have been fully considered but are not found persuasive.

Applicants' position is that claim 1 has been amended to further define components (a), (b), (c) and (d). the soluble matrix can be made of long chain sugar compounds, such as starch, cellulose, and/or glycogen, and PEG. *See* page 7 of the specification. The claims are not limiting to PEG.

Although the claims have been amended, the recitation of "cell components", "cell coating" in claim 1 and "synthetic antigen …is obtained from viruses, bacteria, fungi, tumours, allergens, endogenous tissue and/or the MHC molecule" in claim 5 have not adequate described in the specification as filed. The specification describes membrane fragments from antigen presenting cell. However, the claims encompass any leukocyte stimulation matrix having any cell components, any "cell coating", any "synthetic antigen …is obtained from viruses, bacteria, fungi, tumours, allergens, endogenous tissue and/or the MHC molecule" embedded in a soluble matrix of starch, cellulose, glycogen or polyethylene glycol and at least one carrier such as the ones recited in claim 1. At the time of filing, applicants are not in possession of any leukocyte stimulation matrix having any "cell components", or any "cell coating" or any combinations thereof, any synthetic antigen obtained from any virus, an bacteria, any fungi, any tumor, any allergens, any endogenous tissue, any fragment of any virus from the family of herpes viruses other than membrane fragments of Antigen presenting cell (APC) and viral antigen from cytomegalo virus. It is unclear as to what components of which cell are part of the leukocyte stimulation matrix. With respect to cell coatings, cell has only cell membrane. It is unclear as to what coatings meant by the claims. Is cell coating from leukocyte or from virus? With respect to synthetic antigen *is obtained* from various microorganisms such as viruses, bacteria, fungi, tumors, allergens, endogenous tissue and/or MHC molecules, the specification does not describe

how to obtain synthetic antigen from such microorganisms such as viruses, bacteria, fungi. Doe applicant mean the viral antigen, bacterial antigen, fungal antigen, tumor antigen, allergens, etc is made by recombinant technology?

8. The following new grounds of rejections are necessitated by the amendment filed April 3, 2009 and October 1, 2008.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3, 5, 9, 11-13 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,529,777 (of record, issued June 25, 1996; PTO 892) in view of US Pat No 5,663,051 (of record, issued Sept 2, 1997; PTO 892), WO0027897 publication (newly cited, published May 18, 2000; PTO 892) and WO 96/27657 publication (of record, published Sept 1996; PTO 1449).

The '777 patent teaches a leukocyte stimulation matrix comprising a carrier such as sulfonated polystyrene (see col. 7, line 4, in particular), soluble matrix such as a water soluble polymers or polymeric hydrogels for embedding at least any antigen such as viral antigen, bacterial protein such as lipopolysaccharide (see col. 12, line 25-48, in particular) into the soluble matrix such as for generating a leukocyte stimulation to such antigen such as influenza virus or component of viral antigen such as viral particle structural components that elicit protective immunity (see abstract, col. 12, line 25-67, in particular), and a coupling component such as crosslinker covalent bonding by crosslinking known to those skilled in the art (see abstract, col. 12, lines 35-36, col. 14, line 44-50, col. 11, lines 48-51, in particular). The reference viral antigen can be synthetic using recombinant technology (see col. 12, lines 54-61, in particular). The reference soluble matrix is made of polyethylene glycol (PEG) (see summary of invention, col. 5, lines 9-14, in particular) or cellulose (see col. 4, line 35, in particular).

The invention in claim 1 differs from the teachings of the reference only in that the soluble matrix wherein the coupling component for mediating the binding between the carrier and the at least one component is silane or silane derivative such as alkoxy silane.

The invention in claim 11 differs from the teachings of the reference only in that the soluble matrix is made of 50-90% of a long chain sugar compound and 10-50 % by weight of polyethylene glycol based on the total of long chain sugar compound and polyethylene glycol.

The invention in claim 22 differs from the teachings of the reference only in that the soluble matrix is made of 60-80% of a long chain sugar compound and 40-20 wt % of polyethylene glycol based on the total of long chain sugar compound and polyethylene glycol.

The '051 patent teaches a leukocyte stimulation matrix comprising a housing having at least one inlet opening and at least one outlet opening such as a cell trap tube (see figure, col. 11, line 21-47, in particular) comprising a carrier such as polystyrene latex particle (see col. 17, line 37, in particular), silica bead (see col. 17, line 13, in particular) or glass (col. 16, line 65, in particular), a soluble matrix such as polyethylene glycol (PEG) matrix (see col. 15, in particular), long chain sugar such as polysaccharide or agarose, cellulose, or a combination thereof (see col. 16, line 65-67, in particular), a coupling agent such as silane group with alkyl trimethoxy silane to the silica particle (see col. 13, lines 60 bridging col. 14, lines 1-10, in particular), and at least one component such as IFN-α or β (see col. 18, lines 41-43, in particular), or TGF-β that embedded into the soluble matrix that stimulate leukocyte (see col. 18, line 42, in particular). The reference carrier and at least one component for generating leukocyte stimulation is via covalent binding (see col. 19, line 45-46, in particular).

The WO 00/27897 publication teaches the use of silane or silane derivative such as alkoxy silane as coupling component for mediating the binding between carrier such as polyethylene, polyproylene, glass, metal or tube or catheters (see page 7, lines 29-17, page 9, line 35 through page 11, lines 33, page 16, line 31, in particular). The silane copolymer may be applied to substrate such as polyethylene glycol (see page 12-13, in particular). The advantage of silane copolymer coating improves durability, uniformity, adhesion to silicone and other surfaces that are difficult to coat such as polyethylene and polypropylene (see page 4, Summary of invention, in particular).

The WO 96/27657 publication teaches various carrier or substrates made of biocompatible materials such as glass (see page 9, line 14, in particular), biodegradable polymer such as sponge (see page 9, line 29, in particular) and skin equivalent (see page 16, line 15-20,

references cited therein, in particular). The WO 96/27657 publication further teaches soluble matrix or carrier such as carboxymethylcellulose, and starch (see paragraph bridging pages 6 and 7, in particular). The reference soluble matrix is embedded with a component such as growth factor EGF, TGF-beta, cytokines such as interleukins, GM-CSF, hormone or insulin covalently attached to the matrix or carrier known to one of ordinary skill in the Art (see page 11-12, in particular). The WO 96/27657 publication teaches the reference soluble polymer matrix polyethylene oxide (PEO) is about 97% and 3% of DVB by weight, see page 7, in particular). The advantage of using natural material is that the biodegradability of the polymer can be used to regulate the length of time the growth factor stimulate growth or effect on the cell (see page 10, first paragraph, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple any carrier such as polyethylene and polypropylene or polystyrene of the '777 patent or the glass or sponge of the WO 96/27657 publication by substituting the coupling component or cross-linker known in the skill in the art of the '777 patent or the WO 96/27657 publication with the coupling agent such as silane or silane derivative alkoxy silane as a functional linker as taught by the '051 patent or the WO00/27897 publication to form a leukocyte stimulation matrix comprising polyethylene, polystyrene, glass and/or sponge as the carrier, a polyethylene glycol or cellulose as the soluble matrix, viral antigen as the component embedded in said soluble matrix and silane or silane derivative as the coupling component that mediated the binding between the carrier and the viral antigen.

One having ordinary skill in the art would have been motivated with the expectation of success to substitute one crosslinker with another crosslinker because the WO00/27897 publication teaches the amino alkoxy group of silane will react with the silicone surface and will stabilize with by the reaction of the alkoxy group with water (see page 7, line 3-9, in particular). The advantage of silane copolymer coating improves durability, uniformity, adhesion to silicone and other surfaces that are difficult to coat such as polyethylene and polypropylene as taught by the WO00/27897 publication (see page 4, Summary of invention, in particular).

One having ordinary skill in the art would have been motivated with the expectation of success to use soluble matrix polymer because the biodegradability of the polymer can be used to regulate the length of time the growth factor stimulate growth or effect on the cell as taught by the WO 96/27657 publication (see page 10, first paragraph, in particular) or the viral antigen to the antigen presenting cell for generating a leukocyte stimulation as taught by the '777 patent to elicit

protective immunity (see abstract, col. 12, line 25-67, in particular). Claims 12-13 and 23 are included in this rejection because the tube, i.e., catheter of the WO 00/27897 obviously has two opening such as one inlet opening and one outlet opening (see reference claim 3, in particular). Claim 19 is included in this rejection because the WO 96/27657 publication teaches skin equivalent (see page 16, line 15-20, references cited therein, in particular). It is within the purview of one of ordinary skill in the chemistry art to mix any desire ratio of long chain sugar such as 50 % to 90% of sucrose or dextran by weight (see col. 13, lines 24-27, in particular) with 10 to 50 % of polyethylene glycol (PEG) by weight based on the total weight (100%) of long chain sugar and polyethylene glycol.

11. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,529,777 (of record, issued June 25, 1996; PTO 892) in view of US Pat No 5,663,051 (of record, issued Sept 2, 1997; PTO 892), the WO0027897 publication (newly cited, published May 18, 2000; PTO 892) and WO 96/27657 publication (of record, published Sept 1996; PTO 1449) as applied to claims 1, 3, 5-6, 9, 11-13 and 19-23 mentioned above and further in view of the WO 2004/006951 publication (of record, published January 22, 2004; PTO 1449).

The combined teachings of the '777 patent, the '051 patent, the WO0027897 publication and the WO 96/27657 publication have been discussed supra.

The invention in claim 6 differs from the teachings of the references only in that the leukocyte stimulation matrix wherein the antigen embedded in the soluble matrix is

The invention in claim 18 differs from the teachings of the references only in that the leukocyte stimulation matrix wherein the antigen embedded in the soluble matrix is a virus from the family of herpes virus instead of influenza virus.

The WO 2004/006951 publication teaches a leukocyte stimulation matrix comprising a housing having at least one inlet opening and at least one outlet opening such as a tube (see paragraph 37, in particular), the matrix can be made of organic material such as cellulose (see page 12, paragraph 39, in particular) coated with at least one leukocyte stimulation component such as at least one viral antigen including herpes simplex virus or cytomegalovirus virus (CMV) or a synthetic CMV peptide NLVPMVATV of SEQ ID NO: 4 that engaged in a unique clonotypic lymphocyte receptor (see paragraph 7, paragraph 107, paragraph 158, in particular), at least one component for generating leukocyte stimulation and/or induction of tolerance such as lymphocyte affecting molecule such as T cell co-stimulatory molecule CD80 or CD28 for

stimulating cytotoxic cells or apoptosis inducing molecule for induction of tolerance (see claim 24 of the publication, page 10, paragraph 32, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the viral antigen such as influenza virus in the leukocyte stimulation matrix of the '777 patent, the '051 patent, the WO0027897 publication and the WO 96/27657 publication for the herpes simplex virus or cytomegalovirus virus (CMV) from the WO 2004/006951 publication.

One having ordinary skill in the art would have been motivated with the expectation of success to do this because WO 2004/006951 publication teaches leukocyte stimulation matrix comprising such herpes simplex virus or cytomegalovirus virus (CMV) or a synthetic CMV peptide NLVPMVATV of SEQ ID NO: 4 that engaged in a unique clonotypic lymphocyte receptor is useful for generating leukocyte stimulation and/or induction of tolerance toward such viruses (see claim 24 of the publication, page 10, paragraph 32, in particular).

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.

15. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
May 22, 2009